AF/IFW

PTO/SB/21 (04-07)

Approved for use through 09/30/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/750,376
Filing Date	12/31/2003
First Named Inventor	Keith A. Rindlesbach
Art Unit	1616
Examiner Name	Frank I. Choi
Attorney Docket Number	01845-22396

Total Number of Pages in This Submission

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☑ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):
  - Return Postcard
  - Check for $250.00

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Thorpe North & Western, LLP		
Signature			
Printed name	Gary P. Oakeson		
Date	08/17/2007	Reg. No.	44266

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	Brenda Wiseman		
Typed or printed name	Brenda Wiseman	Date	08/17/2007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPELLANT:	Keith Rindlesbach
SERIAL NO.:	10/750,376
FILING DATE:	12/31/2003
CONF. NO.:	4892
FOR:	METHOD FOR REVERSING ALZHEIMER DEMENTIA
ART UNIT:	1616
EXAMINER:	Frank I Choi
DOCKET NO.:	01845-22396

CERTIFICATE OF DEPOSIT UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being transmitted via facsimile to the USPTO or being deposited with the United States Postal Service with sufficient postage as first class postage in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

8/17/07
Date of Deposit

Brenda Wiseman
Brenda Wiseman

APPELLANTS' APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Mail Stop Appeal Brief – Patents

Sir:

Appellants submit this Appeal Brief in connection with their appeal from the final rejection of the Patent Office, mailed January 26, 2007, in the above-identified application. A Notice of Appeal was filed on July 19, 2007.

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest of this application is Keith A. Rindlesbach, 2324 West 11800 South, Riverton, Utah, 84065.

II. RELATED APPEALS AND INTERFERENCES

Appellants and Appellants' legal representatives know of no other appeals or interferences that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-20 remain pending. The claims on appeal in this application are claims 1-20.

IV. STATUS OF AMENDMENTS

Amendments to the presently pending claims have been made since the Office Action mailed on January 26, 2007, by which the final rejection of the pending claims was made, however, the amendments have not been entered by the Examiner. Thus, the claims under appeal are those which were pending prior to the most recent claim amendments.

V. SUMMARY OF CLAIMED SUBJECT MATTER

1. (Original) A method of reducing effects of Alzheimer's Dementia in a patient, comprising steps of (page 12, line 4-5):

a) administering a does of amoxicillin and Vitamin B_{12} to a patent (page 12 line 6);

b) administering a dose of indomethacin to the patient (page 12 line 7);

c) administering a dose of S-andenosyl-L-methionine and selinium to the patent (page 12 lines 8-9); and

d) administering a dose of at least one of ibuprofen and aspirin to the patient (page 12 lines 10-11).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues presented for review are:

a. whether the application fails to comply with the enablement requirement under 35 U.S.C. § 112, first paragraph; specifically, whether the application's specification would require one of ordinary skill in the art to perform undue experimentation.

VII. ARGUMENT

A. Prosecution History

The present application was filed as an original utility application on December 31, 2003 under the title A METHOD FOR REVERSING ALZHEIMER DEMENTIA. Twenty claims were presented. The application was assigned Serial No. 10/750,376.

In the first Office Action mailed July 5, 2006, the Examiner rejected claims 1-20 under U.S.C. § 112, first paragraph for various reasons. Specifically, the Examiner stated that although information as to doses was contained within the specification, the working examples appeared to be prophetic in nature. Additionally, the Examiner stated that the claims were too broad in that they claimed a method where dosing could occur up to 18 hours after dosing one of the ingredients. The Examiner argued that such claims would require one of ordinary skill in the art to do undue experimentation to determine what doses, dosing intervals, order of dosing, etc. would be effective.

Appellants submitted a response to the Patent Office on November 6, 2006 pointing out that the Examiner assumed that the examples were prophetic without any indication of such from the Appellant, and that nothing in the examples stated or implied that the examples were prophetic. In addition, Appellants explained that the examples have sufficient detail to provide what the Appellant considered to be the invention, and that the examples provide a sufficient dosing regimen to enable it to be followed without undue experimentation. Appellant also emphasized that a person could follow the regimen exactly if they chose to.

A second Office Action was made final and mailed on January 26, 2007. In that Action, the Examiner maintained the U.S.C. § 112, first paragraph, rejection for

claims 1-20. Specifically, the Examiner set forth the same arguments and added that the specification provided insufficient evidence that the combination would be effective in reducing Alzheimer's dementia. In response to Appellant's arguments, the Examiner argued that Appellant provided no evidence refuting the conclusion that the examples were prophetic in nature. The Examiner reasoned that Appellant stated what may occur or what was intended to occur and not that treatment was administered to a patient with a resulting reduction in Alzheimer's dementia. The Examiner reasoned that the enablement requirement was not satisfied although treatment methods were disclosed in the specification.

In an effort to expedite prosecution, a telephone interview was conducted involving the Examiner and Counsel for the Appellant. In the interview, the Examiner indicated that the scope of the claims should be more narrowly tailored to the treatments set forth in the examples and indicated that a declaration would be required to address the "prophetic" nature of the examples. The Examiner suggested that the declaration indicate that the examples were not prophetic in nature, and include additional information as to the actual effects observed in the treatment of the Alzheimer's patient. During the conversation it was also agreed that if the amendments and declaration did not put the claims in condition for allowance, the amendments would be entered, the finality of the office action removed, and a telephone interview would be initiated by the Examiner.

Accordingly, Appellants submitted a response to the second Office Action on March 26, 2007. In the response, Appellants amended claim 1, as suggested by the Examiner, by incorporating dependent claims 2-10 and 16 to reflect the treatment outlined in example 1 of the application. Accordingly, claims 2-10 and 16 were cancelled. This was an amendment that the Appellant did not think was warranted by

current U.S. patent law, but did so for economy purposes to put the case in condition for allowance. In addition, as per the Examiner's suggestion, Appellants submitted a declaration indicating that the examples were not prophetic in nature (which the Appellant also does not believe was necessary), and that a patient treated in accordance with the example had experienced a decrease in Alzheimer's dementia through treatment according to the practice of example 1 of the specification . The declaration further included information as to the effects observed in the patient as the patient was treated in accordance with the combination and method disclosed in the application.

In response to Appellant's response of March 26, 2007, the Examiner submitted an Advisory Action on July 19, 2007. In the Advisory Action, the Examiner failed to enter the amendments or declaration as agreed upon in the telephone interview, and indicated that the request for reconsideration did not place the application in a condition for allowance since the amendments and declaration had not been entered. The Examiner accordingly rejected the claims for the reasons set forth in the Final Office Action. The Advisory Action indicated that the amendments were not entered because the Examiner felt they raised new issues that would require further consideration and/or a search; and they were not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

The Advisory Action further indicated that the declaration was not entered because the Examiner felt the Appellant had failed to provide a showing of good and sufficient reasons why the declaration was necessary and was not earlier presented. The Advisory Action also indicated that the declaration was not entered because it would require further consideration and/or a search due to the fact that the declaration

indicated that the examples were not hypothetical, but provided no data or records to support that conclusion. It should further be noted that the Examiner did not make an attempt to initiate a telephone interview with Appellant's Counsel as was previously agreed upon.

After receiving the Advisory Action on the present application, particularly where the Examiner failed to enter the amendments and declaration after suggesting that they be submitted, Appellants decided it would be beneficial to appeal the present claims. Accordingly, Appellants filed a Notice of Appeal on July 19, 2007.

B. Appellants' invention

Appellants' invention provides a method of reducing the effects of Alzheimer's dementia. As such, the method can comprise the steps of: a) administering a does of amoxicillin and Vitamin B_{12} to a patent; b) administering a dose of indomethacin to the patient; c) administering a dose of S-andenosyl-L-methionine and selinium to the patent; and d) administering a dose of at least one of ibuprofen and aspirin to the patient.

As such, the method and dosage disclosed in the application are not meant to cure Alzheimer's disease, but are provided as a means for lessening the cognitive impairment and other symptoms associated with the disease.

It should be noted that the claimed method requires the administration of four (4) different drugs/components to a patient, which in this particular field, provides very narrow claim coverage.

C. Rejections Under 35 U.S.C. § 112, first paragraph

1. The enablement requirement

The Examiner has rejected all of the pending claims under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. As defined in § 2164 of the M.P.E.P., the enablement requirement provides that the specification describe how to make and use the invention. A test to determine whether a specification meets the enablement requirement was set forth in *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) and has been interpreted to require that a specification teach a person skilled in the art how to make and use an invention without undue experimentation. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Several factors are provided in § 2164.01(a) of the M.P.E.P. to help an Examiner determine if any experimentation would be undue. The factors include:

(A) The breadth of the claims;
(B) The nature of the Invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404. In addition, M.P.E.P. § 2164.05 provides that a § 112 rejection should not be given based on any one factor alone, but that the evidence should be considered as a whole.

2. The Examiner's rejections

The Examiner bases his rejection on the belief that the examples provided in the application are hypothetical or prophetic. The Examiner further bases his rejection on the assertion that the application would require one of ordinary skill in

the art to perform undue experimentation to determine the appropriate treatment method to effectively reduce the effects of Alzheimer's dementia. The Examiner uses these two arguments along with the fact that the state of the art regarding Alzheimer's treatments is limited to present evidence that the claims in the application are not enabled.

3. Working example

M.P.E.P. § 2164.02 provides that enablement does not depend on whether an example is present in the application and that if presented, an example may be either working or prophetic, the difference being whether or not the example was based on worked performed. However, existence of a working example is a strong indication of enablement. As stated in § 2164.02 of the M.P.E.P.:

> "A single working example in the specification for a claimed invention is enough to preclude a rejection which states that nothing is enabled since at least that embodiment would be enabled."

Appellants contend that the Examiner erred by failing to recognize the examples provided in the application as working examples and by failing to enter the declaration in the record which would have established the examples as such. In the Office Actions, the Examiner evidenced his § 112 rejection, in part, based on the conclusion that the examples were prophetic in nature. However, as argued and stated on the record in the Appellant's first response, nothing in the examples state or imply that the examples are prophetic. In contrast, the summary of the invention clearly indicates that "the present invention provides a method of reducing the effects of Alzheimer's dementia" while the examples section indicates that "the following examples illustrate embodiments of the invention that are presently known." (underlining added). The language of these sections states that the examples are

based on results of work actually performed and are not prophetic as the Examiner claims.

The Examiner assumed the examples were prophetic, as indicated in the second Office Action, because the application did not include a positive assertion that treatment had been performed on a patient with a resulting decrease in Alzheimer's dementia. As such, the Examiner suggested in the telephone interview that an affidavit be provided indicating the examples were not prophetic and were based on work performed and additionally including actual effects observed in the treatment of a patient. Accordingly, Appellant provided the Examiner with a declaration indicating that the treatment method had been performed on a patient under the supervision of a physician, and further detailing some of the effects observed during and following the treatment. The Examiner, however, failed to enter the declaration in the record claiming that while the declaration indicated that the example was not prophetic, it did not provide data or records to support that conclusion. It is noted that it is the Appellant's position that a declaration was never necessary, and thus, the failure of the Examiner to enter this declaration is irrelevant. The Appellant has gone on the record several times reiterating that the example was not prophetic.

This being said, in failing to enter the declaration, the Examiner applied a standard for evidence inconsistent with the M.P.E.P. Section 2164.05 of the M.P.E.P provides that in responding to an enablement rejection, the evidence provided by the Appellant "need not be conclusive but merely convincing to one skilled in the art." In addition, the court has provided that only a reasonable correlation need be established between a compound's activity and an asserted therapeutic use. *Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985). As discussed in M.P.E.P. § 2107.03(III), a good example of this standard includes situations where a compound's therapeutic

utility relating to humans can be supported by non-human testing, such as in vitro or animal testing. Appellant asserts that the declaration, prior assertions, and the application itself, each provide convincing evidence that a reasonable correlation exists between Appellant's treatment methods and a resulting reduction in Alzheimer's dementia, and as such, the Examiner erred in refusing to enter the declaration, and/or removing this rejection based on the Appellant's description in the specification and repeatedly stating on the record that the example was not prophetic.

The failure to enter the declaration resulted in the continuation of Examiner's argument concerning Appellant's examples, and thus denied Appellant's evidence (i.e. working examples) toward establishing the enablement requirement as being fulfilled. Further, it is the Appellant's position that such a declaration was never needed to establish that the example was a real example conducted under the supervision of a doctor.

4. Undue experimentation

M.P.E.P. § 2164.01 provides that it is not whether experimentation is necessary, but whether any necessary experimentation is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). The section further provides that even complex experimentation may not be undue if such experimentation is typically engaged in by those in the art, *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), and that even an extended experimentation period may not be undue if sufficient guidance and direction is provided to a skilled artisan. *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150,153 (CCPA 1977).

The Examiner contends that the treatment method disclosed in the application requires undue experimentation because the claims contain limitations to a method

where dosing occurs over an 18 hour period, and as such, requires a person skilled in the art to perform undue experimentation to determine the doses, dosing intervals, order of dosing, etc. necessary to effectively reduce the effects of Alzheimer's dementia. The rejection is augmented by the Examiner's belief that the examples set forth in the application would not provide the relief claimed in the application. This is evidenced in the second Office Action where the Examiner argues that, "[Appellant] has provided no evidence that the drugs used in the claimed invention exhibit said characteristics much less that any combination or interval of dosing of the given drugs would be effective in reducing Alzheimer's dementia."

Appellants contend that the Examiner erred in rejecting the application based on undue experimentation for several reasons. First, the amount of direction provided in the specification was sufficient to allow one skilled in the art to make and use the invention while performing minimal, if any, experimentation. Second, if any experimentation is necessary, such experimentation is typically engaged in by those skilled in the art most closely associated with the application. Additionally, there is an example that teaches one skilled in the art how to practice the invention with exact dosages, timing, etc., e.g., an example that establishes the best mode of practicing the invention at the time of filing.

As asserted, the amount of direction provided in the specification was sufficient to allow one skilled in the art to make and use the invention. An application is required only to teach a person skilled in the art how to make and use the claimed invention. In contrast, an application is not required to "enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment...." *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir.

2003). The application in question claims reducing the effects of Alzheimer's dementia through the administration of several compounds.

As indicated in Appellant's first response, the examples disclose a treatment method for administering the several compounds including the dosing amounts, dosing intervals, and order of dosing. As specifically argued, the treatment method could be followed exactly to achieve the claimed result, thereby eliminating any experimentation. Additionally, the application provides multiple brand-name products that could be used for the compounds, further reducing the need for any experimentation. The Examiner's contention is further diminished when the teachings of the specification are considered in combination with the examples that are based on a successful implementation of the treatment method, as specified in the declaration, where the result was a reduction in the effects (or symptoms) of Alzheimer's dementia as claimed. Appellant therefore asserts that the specification does teach a person skilled in the art to make and use the invention without requiring undue experimentation.

In addition, if any experimentation that is necessary, it is the type that is typically engaged in by those skilled in the art or skilled in the art most closely associated with the invention. The Examiner specifically argues that experimentation is undue because such experimentation would involve determining the doses, dosing intervals, order of dosing, etc. necessary to effectively reduce the effects of Alzheimer's dementia. However, such experimentation requirements are the type typically engaged in by those skilled in the art i.e. those engaged in the development of disease treatments. In other words, those engaged in the development of disease treatments routinely experiment with compounds to determine the doses, dosing intervals, order of dosing, etc. necessary to effectively treat and/or cure diseases, and

as such, any necessary experimentation would not be undue. At a minimum, by specifying the compounds, including brand-names, and dosing ranges and intervals for those compounds, the application provides sufficient guidance and direction to avoid any necessary experimentation from being undue. Further, as noted previously, there is a specific example that can be followed exactly without deviation which could be administered by even an unskilled person.

5. Viewing the evidence as a whole

Viewing the evidence as a whole as in accordance with M.P.E.P. § 2164.05, the working examples provided in the application that specifically provide a treatment method including the doses, dosing intervals, and order of dosing of the several compounds establish that the application fulfills the enablement requirement as set forth in 35 U.S.C. § 112.

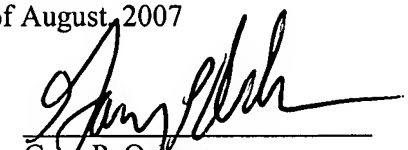
D. Conclusion

Appellants respectfully submit that the claims on appeal are in compliance with the enablement requirement under 35 U.S.C. § 112, first paragraph. Particularly, Appellants submit that the examples provided in the application are based on treatment provided to a patient and sufficiently disclose the invention so that undue experimentation is not required.

For at least these reasons, Appellants respectfully request that the Board of Appeals reverse the rejection and remand the case to the Examiner for allowance.

Please charge any additional fees except for Issue Fee or credit any overpayment to Deposit Account No. 20-0100.

Dated this 17th day of August, 2007



Gary P. Oakeson
Attorney for Appellants
Registration No. 44,266

THORPE NORTH & WESTERN, LLP
8180 South 700 East, Suite 350
Sandy, Utah 84070
(801) 566-6633

VIII. CLAIMS APPENDIX

1. A method of reducing effects of Alzheimer's Dementia in a patient, comprising steps of:

a) administering a dose of amoxicillin and Vitamin B_{12} to a patient;

b) administering a dose of indomethacin to the patient;

c) administering a dose of S-adenosyl-L-methionine and selinium to the patient; and

d) administering a dose of at least one of ibuprofen and aspirin to the patient.

2. The method of claim 1, wherein the step of administering S-adenosyl-L-methionine and selenium occurs from about 4 hours to about 18 hours after the administration of amoxicillin.

3. The method of claim 1, wherein the dose of amoxicillin administered to the patient is from about 100 mg to about 1750 mg.

4. The method of claim 3, wherein the dose of amoxicillin administered to the patient is from about 500 mg to about 1000 mg.

5. The method of claim 1, wherein the dose of Vitamin B_{12} administered to the patient is from about 100 mg to about 3000 mg.

6. The method of claim 5, wherein the dose of Vitamin B_{12} administered to the patient is from about 250 mg to about 2000 mg.

7. The method of claim 1, wherein the dose of indomethacin administered to the patient is from about 25 mg to about 200 mg.

8. The method of claim 1, wherein the dose of S-adenosyl-L-methionine administered to the patient is from about 50 mg to about 600 mg.

9. The method of claim 8, wherein the dose of S-adenosyl-L-methionine administered to the patient is from about 100 mg to about 400 mg.

10. The method of claim 1, wherein the dose of selenium administered to the patient is from about 50 mg to about 200 mg.

11. The method of claim 1, further comprising a step of administering clavulanate potassium to the patient.

12. The method of claim 1, further comprising a preliminary step of treating the patient for a preexisting fungal infection.

13. The method of claim 12, further comprising step of administering fluconazole to the patient.

14. The method of claim 12, further comprising step of administering a culture of acidophilus to the patient.

15. The method of claim 1, further comprising a preliminary step of administering nicotinamide adenine dinucleotide to the patient prior to administering amoxicillin.

16. The method of claim 1, wherein the step of administering amoxicillin and Vitamin B_{12} occurs on at least two separate occasions and at least 1½ hours apart.

17. The method of claim 1, further comprising a step of administering a cephalosporin antibiotic to the patient.

18. The method of claim 1, further comprising a step of administering Ca, Mg, and Vitamin D to the patient.

19. The method of claim 1, further comprising a step of administering Vitamin B_1, Vitamin B_2, Vitamin B_6 or combinations thereof to the patient.

20. The method of claim 1, further comprising a step of administering flax oil to the patient in a therapeutically effective amount.

IX. EVIDENCE APPENDIX

(No matter presented)

X. RELATED PROCEEDINGS APPENDIX

(No matter presented)